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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,235

10/27/2003

N. Sandor Racz

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

07/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No. 10/694,235	Applicant(s) RACZ ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10, 11, 13, 19, 22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/26/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office Action after the Request for Continued Examination based on the 10/694235 application filed October 27, 2003. Claims 1-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27, and 28 as amended are currently pending and considered below.

Claim Objections

1. Claim 2 is objected to because of the following informalities: the phrase “non cutting” should be replaced with -- non-cutting -- for consistency within the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6, 8, 9, 12, 14-18, 20, 23, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2002/0099335 A1 to Zohmann.

Regarding the above claims, Zohmann discloses a flexible spinal needle assembly (10) comprising a support needle (4) having a first end defining a non-cutting piercing pencil-point tip (54) and a support hub (40) with a first attach structure (45) and a detach structure (47), a flexible needle (6) slidably mounted on the support needle in such a way as to expose the tip (Fig. 1) wherein the flexible needle can puncture the

dura and provide feedback (Paragraph [0016]) and the flexible needle has a hub (60), a second attach structure (62) and a detach structure (67). Zohmann further discloses a hub (40) capable of being secured to the patient, as well as a kink sleeve disposed about a portion of the flexible needle (65).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann in view of USPN 5,116,323 to Kreuzer et al.

Zohmann discloses the invention of claims 4 and 16 as described above, however Zohmann is silent to the connections being a luer lock. Kreuzer et al disclose a catheter assembly having luer lock connections between the catheter and needle structures. It would have been obvious to one of ordinary skill in the connector art to modify the friction fit connection of Zohmann with a luer lock connector as taught by Kreuzer et al in order to provide an improved and more secured connection between the catheter and the needle.

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann.

Regarding claim 28, Zohmann teaches all the limitations of claim 27 as described above, but fails to explicitly teach that the flexible needle body comprises a medical grade plastic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the needle out of a medical grade plastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

9. Applicant's arguments filed November 26, 2007 have been fully considered but they are not persuasive.

Regarding applicant's argument that the art of Zohmann does not teach all of the limitations of the independent claims, the examiner respectfully disagrees and directs the applicant to the above rejection for a thorough description of the rejection. Further regarding applicant's suggestion that the "introducer" (6) of Zohmann is not a "flexible needle" as claimed by applicant, the examiner maintains that all elongate devices will maintain some degree of flexibility and thus the "introducer" of Zohmann is, indeed, a "flexible needle".

Regarding applicant's argument that multiple "slight modifications" would have to be made in order to use the device of Zohmann to perform the function of the instant invention, the examiner notes that the dimensions of the devices would depend on the patient and thus the lengths of the devices would already vary. Further regarding applicant's argument that the reference fails to show a tip on the flexible needle that permits resealing of the dura mater, it is noted that this feature is not recited in the rejected claim(s), only the diameter of the flexible needle is discussed in this regard, and the introducer of Zohmann is similar in diameter to the flexible needle of the instant application. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763